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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,848	03/23/2001	Stefan Jaroeh	SCH 1707	8039

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EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

10

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,848

Applicant(s)

JAROCH ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-17 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-15 is/are rejected.
- 7) ☒ Claim(s) 16 and 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

The 112, second rejection of the phrase "pharmaceutical agent" in claims 6-7 and the rejection of claims 6 and 8 for the lack of the term "effective amount" are rendered moot in light of applicant's amendment at paper no. 9/C.

(old rejections)

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while providing enablement for imidazole, indole, isooxazole, isothiazole, furan, oxadiazole, oxazole, pyrazine, pyridazine, pyrimidine, pyridine, pyrazole, pyrrole, tetrazole, thiazole, triazole, thiophene, thiadiazole, benzimidazole, benzofuran, benzoxazole, isoquinoline, and quinoline, piperidine, pyrrolidine, morpholine, thiomorpholine, hexahydroazepine, and piperazine, does not reasonably provide enablement for R14 and R15 coming together with the nitrogen atom to form all 5- to 7-membered saturated heterocycle with can be optionally substituted as claimed in claim 1, page 3, lines 21-24, and does not reasonably provide enablement for R4 and R5 in claim 1, lines 13-14, page 2 and all other occurrences, equal to all five or 6 membered carbocyclic rings, which can be

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substituted with NR14R15 for reasons of record at paper no. 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-7, 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record at paper no. 7.

A. In claim 1, page 2, lines 13-14, and all other occurrences throughout claims 1-7 and 9, the phrase "R4 and R5 together with 2 adjacent carbon atoms form a five-or six-membered carbocyclic compound, which is optionally substituted with NR14R15" is indefinite. This phrase is so broad as to render the claim meaningless. Which carbocyclic rings is the applicant claiming?

B. In claim 1, page 3, lines 16-18, and all other occurrences throughout claims 1-7 and 9, the phrase "5- or 6-membered heteroaryl with 1-4 nitrogen, oxygen or sulfur atoms, which can be annelated with benzene, whereby the aryl radical and the heteroaryl radical.." is indefinite. The phrase is so broad as to render the claim meaningless. Which heteroaryl rings are the applicants claiming?

C. In claim 1, page 3, line 21-25, page 3, the phrase "R14 and R15 together with the nitrogen atom form a 5- to 7-membered saturated heterocycle, which can contain another oxygen, nitrogen or sulfur atom and can be substituted with C1-4 alkyl or a phenyl, benzyl or benzoyl radical that is optionally substituted with halogen, or an unsaturated 5-membered heterocycle, which can contain 1-3 N atoms and can be substituted" is indefinite. The phrase is so broad as to render the claim meaningless. Which heterocycle rings are the applicants claiming?

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D. In claim 9, the phrase "neurodegenerative diseases" is indefinite. The phrase is so broad as to encompass a wide range of diseases. Which neurodegenerative diseases is the applicant claiming?

keep

(new rejections)

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 13, and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of treating all diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement.

keep

The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the

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invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the fifth Wands factor, level of predictability in the art is nonexistent since the applicant does not test the affect of these compound on the diseases claimed. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not test any compounds for their affect on the diseases claimed. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

✓ Claim(s) 15 in part is rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Inhibiting neuronal NDS is a mechanism. The disease being treated by this inhibition is not stated. The specification must contain one practical utility in currently available form. The inhibition of an enzyme must be related to a disease that needs to be improved and this disease needs to be recited. There is

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no reasonable assurance that these compounds will have all of the alleged properties or have the applicants supplied the supporting data. The applicant is referred to *In re Fouché* 169 USPQ 429 ccpa, 1971, MPEP 716.02 B. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte Foreman* 230 USPQ 546 (Bd. Of App. And Inter 1986).

Claims 16-17 are objected to because they are based on a rejected claim.

Response to Applicant's Remarks

112, first paragraph rejection

The applicant asserts that claims 1-7 and 9 are fully enabled because of the recitation of specific examples of the 5 to 7 membered saturated heterocycle both in its unsubstituted and substituted forms. However, the examiner notes that this is not sufficient enablement for the full scope of the heterocycle rings claimed for the following reasons: Such a scope includes rings yet to be discovered or synthesized. For example 5 oxygen atoms or sulfur atoms in one ring have not been made – in addition, heterocycle can include O, S, N, and Se with at least one carbon atom without the appropriate configuration of each atom. Working examples and test results on the diseases claimed are not provided for the full markush grouping of these heterocyclic rings.

112, second paragraph rejection

The applicant asserts that the phrases R4 and R5 together with 2 adjacent carbon atoms form a five- or six-membered carbocyclic compound, which is optionally

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substituted with NR14R15", "5- or 6-membered heteroaryl with 1-4 nitrogen, oxygen or sulfur atoms, which can be annelated with benzene, whereby the aryl radical and the heteroaryl radical", and "R14 and R15 together with the nitrogen atom form a 5- to 7-membered saturated heterocycle, which can contain another oxygen, nitrogen or sulfur atom and can be substituted with C1-4 alkyl or a phenyl, benzyl or benzoyl radical that is optionally substituted with halogen, or an unsaturated 5-membered heterocycle, which can contain 1-3 N atoms and can be substituted" are not indefinite because they are allegedly art recognized. However, the examiner notes that such a scope includes rings yet to be discovered or synthesized. For example 5 oxygen atoms or sulfur atoms in one ring have not been made – in addition, heterocycle can include O, S, N, and Se with at least one carbon atom without the appropriate configuration of each atom.

The applicant traverses the 112, second paragraph rejection of the phrase "neurodegenerative diseases" asserting that this phrase is merely broad, but is well recognized in the art. The examiner notes however, that the scope of the invention sought to be patented cannot be determined from this very broad language of the claims with a reasonable degree of certainty and therefore should be rejected under 35 U. S. C. 112, second paragraph. In re Wiggins, 488 F.2d 538, 179 USPQ 421 (CCPA 1973).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson

March 7, 2002

Alan L Rotman
ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600